The GlideScope®
Video Intubation System

Operator & Service Manual

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I. GENERAL INFORMATION

1 Introduction

The GlideScope® Video Intubation System is a camera laryngoscope that displays an unobstructed view of the vocal cords on a monitor. It is ideal for a variety of situations and airways when used by physicians and healthcare professionals.

"Standard of Care"

Video assisted intubation will become the new standard of care.

The GlideScope® Video Intubation System Includes:

1 Integrated GlideScope® Video Laryngoscope
2 Integrated control unit with 7" LCD TFT high resolution monitor
3 Mobile, height adjustable stand
4 Power supply cord (Control unit → Power)
5 Video cable (Control unit → GlideScope® Video Laryngoscope handle)
6 Operator & Service Manual
7 Laminated Reference Card – "General Use & Cleaning"

Optional Accessories:

~ Video adaptor cable
~ IV Pole mount
~ Control Unit with out 7" LCD high resolution monitor

1.2 Features

- The GlideScope® video laryngoscope is made of a robust and durable medical grade plastic and is reusable
- The blade has a 18mm maximum dimension at any point thus facilitating the passage of the GlideScope into the airway
- A digital video camera is embedded within the blade, providing an unobstructed view of the vocal cords and allowing one to see exactly have the ET tube placement is proceeding
- The camera is equipped with a proprietary anti-fogging device
- Mounted beside the camera are two synchronized lighting devices to provide continuous illumination during the intubation
- The GlideScope® video laryngoscope handle is easy to adapt to and use since its shape is similar to that of traditional laryngoscopes
- The control unit can be adjusted to provide a clear view from a variety of angles
- The GlideScope® video laryngoscope can be easily detached from the video cable for sterilization
- The GlideScope® is equipped with a cover plug to protect the multi pin connector during sterilization
- An easily accessible quick reference card containing general use and cleaning instructions that may be attached to the control unit

1.3 Specifications

Line Voltage Range: 100-240 VAC, 50 & 60 Hz
Line Current: 0.85 A max
Power Cord: 457 cm (15')
Power Plug: Hospital Grade
Line Protection: 2A Fuse, Internal

Approximate Size of Control Unit:

Height: 191 mm (7.5")
Width: 305 mm (12")
Depth: 101 mm (4")

Weight:	Control Unit	1 Kg (2lbs)
	~with GlideScope® video laryngoscope & video cable	1.5 Kg (3 lbs)
	~with power cord	2 Kg (4.4 lbs)
	~with five leg telescoping stand & tilt mount	3 Kg (6.6 lbs)

Class I EQUIPMENT

Caution: Electrical Shock Hazard
REFER SERVICING TO QUALIFIED PERSONNEL

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class A and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, is very unlikely to cause harmful interference to other device(s) in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between equipment
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) is/are connected
- Consult the manufacturer or field service technician.

Controls:

Front panel membrane switch:

- POWER: applies/withholds power to unit
- MENU: steps through menu options for LCD display
- UP: allows you to adjust options within the menu
- DOWN: allows you to adjust options within the menu

Display:

NTSC Video 320 x 240 LCD TFT Panel

Power Indicator Light:

- Green LED on front panel

Approvals:

FDA Registered 2891, 2892
~Class 1 Device
Health Canada License No. 31781
~Class 2 Device
UL 2601-1, IEC 601.1/601.2.18

CSA 22.2 No. 601.1 Approved
IEC 601.1 Approved
CE Requirement met

II. INSTALLATION

2.1 Initial Inspection

Unpack the GlideScope® video intubation system upon receipt and inspect the unit for any obvious physical damage that may have occurred during shipment. It is recommended that a qualified biomedical engineer or other professional thoroughly familiar with electronic medical devices perform this inspection. If the unit is damaged, notify the carrier and your Saturn Biomedical representative immediately. If the initial inspection results are satisfactory, a functional check should be performed.

2.2 Functional Check

The unit shall produce the results explained in the following steps exactly as indicated. Failure to do so indicates that the device is not to be used until necessary repairs are made.

1. Connect the power plug to the power entry module on the bottom of the control unit and secure the cord with the wire clip. Plug the other end of the power supply cord into a properly polarized and grounded power source whose voltage and frequency characteristics are compatible with those listed on the nameplate of the unit.

2. Connect the video cable to the bottom, front, right of the control unit. Insert the other end of the cable into the GlideScope® video laryngoscope and place the GlideScope® in the cradle on the side of the control unit.

3. Turn on the unit by pressing the POWER button and observe the view from the GlideScope®. Note that there should be a small portion of the upper left hand corner and the top of the screen that will be black. The black image is a section of the GlideScope® blade. This view acts as a frame of reference during the intubation and assures that the orientation of the image is correct in the monitor.

2.3 Controls and Connectors

Controls:

Monitor: **POWER** button – when first pressed the green indicator light beside the button will light up and the GlideScope® System will activate. When pressed a second time the GlideScope® will power down.

MENU button – when pressed will allow selection of the following options:
Brightness – TV system – NTSC/PAL/AUTO
Contrast – display mode – screen size reset
Colour
Tint
Up/down – image will be upside down (Not Advised)
Mirror – mirror image on the control unit (Not Advised)

- In order to select one of the above options simply continue to press the MENU button until the one you desire is highlighted (turns from green to yellow)
- UP or DOWN buttons – once you have selected your choice with the MENU button you may use these buttons to make the needed adjustments

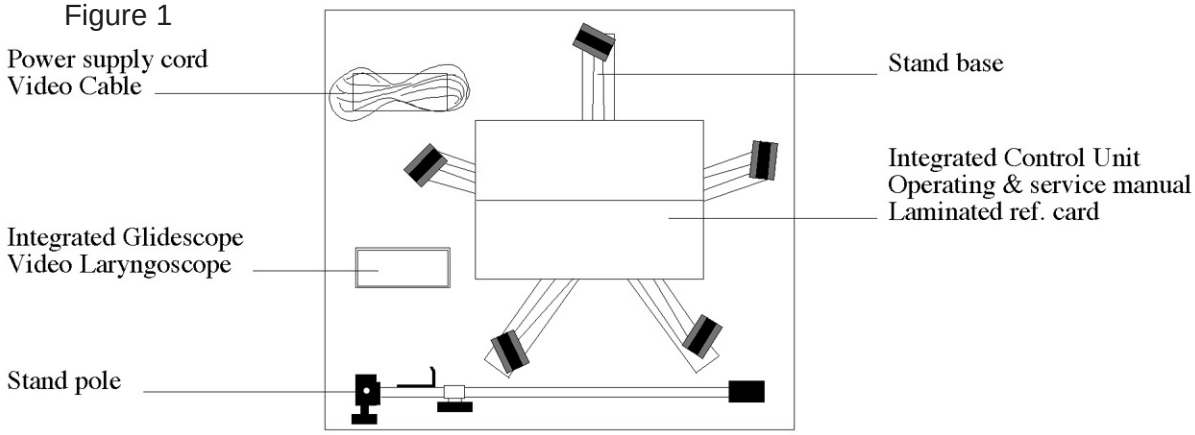
Connectors:

Video Cable – connects the GlideScope® video laryngoscope to the control unit

Power Supply Cord – connects the control unit to the A.C. power source

2.4 Unpacking, Assembly & Installation

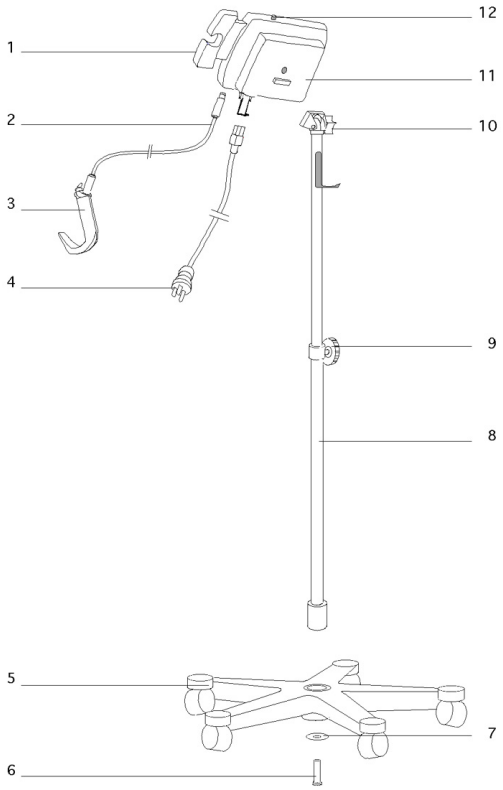
Figure 1



1. Remove the centre box containing the integrated control unit, operating and service manuals, and laminated reference card and set aside.
2. Remove the smaller box containing the integrated GlideScope® video laryngoscope handle and set it aside.
3. Remove the base of the stand and the pole section of the stand. Remove the bolt and washer from the bottom of the pole and insert that end into the top of the base. Once in place screw the bolt and washer back into place to secure the pole to the base of the stand. The stand is easily assembled with the use of an adjustable wrench.
4. To adjust the height of the stand simply loosen the black knob and raise or lower and then tighten.
5. Remove the integrated control unit from its box and packing material and attach it to the stand by holding the control unit against the screw on the top of the stand and turning the dial to tighten. Tilt the control unit upward at an angle of 10-15 degrees. The control unit can be mounted on a retractable arm if so desired.
6. Remove the video cable from the outside shipping box and insert one end into the front port on the lower side of the control unit.
7. Remove the integrated GlideScope® video laryngoscope handle from its box and insert the other end of the video cable into the port.
8. Attach the laminated quick reference card, containing general use and cleaning instructions by squeezing the metal clasp on the bottom of the control unit and hooking the card with it and reattaching the power cord retainer wire to the control unit.
9. Remove the power supply cord from the outside shipping box and insert the female end into the back port on the lower side of the control unit. Move the power cord retainer wire clip over the end of the plug to secure the power cord in place.
10. Line up the black locking knob and the power cable hook on the stand and then wrap the power cord around both for neat storage.
11. The system can now be tested by pressing the power switch on the Control Unit face. The menu items will be set at the middle range and the brightness control may be increased at this stage to an 18-20 unit level.
12. The system is now ready for clinical use.

Do not attach articles on the GlideScope® stand that are not related to the GlideScope® System!

Figure 2



1. GlideScope® cradle
2. Video cable
3. GlideScope® Video Laryngoscope
4. Power Cord
5. Five wheel stand base
6. Hex bolt
7. Flat washer
8. Pole section of Stand
9. Locking knob for height adjustment
10. Adjustable locking knob
11. Control Unit
12. Video output

III. OPERATING INSTRUCTIONS

3.1 Intended Use

The GlideScope® System is intended to be used by qualified medical professionals to obtain a clear unobstructed view of the vocal cords for medical procedures. The GlideScope® may be useful for the following procedures:

- Grade I-IV intubations
- Teaching purposes
- Nasogastric and orogastric tube placement
- Visualization and assessment of the oropharynx
- Foreign body removal
- Epiglottitis
- Nasal Tracheal Intubation

3.2 Clinical Application Instructions

Control Unit Operation

1. Control Unit Menu settings are usually placed in the midrange of the operational scale and except for an increase in brightness.
2. The Control Unit may be attached to an Anesthetic machine arm, an IV pole, an overhead suspension arm or may be placed on the right or left side of the patient in direct view.
3. The angulation of the screen is adjusted for best viewing.

GlideScope® Insertion

1. The GlideScope® is inserted down the **midline of the tongue**, the epiglottis is readily apparent. The blade in this example is inserted to lift the epiglottis directly Miller style.

2. The epiglottis is lifted indirectly with the blade in the vallecula, Macintosh style.

3. The GlideScope® blade may pass down the right side of the tongue if a sweeping technique is attempted but this will leave less room for tube passage. Passage on the left side of the tongue may partially compromise the LED light.

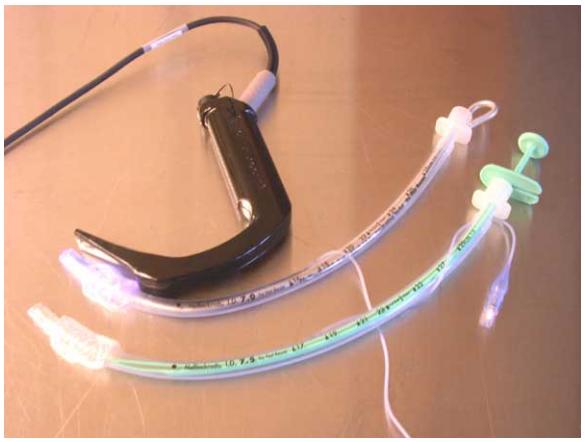
"The midline is golden with the GlideScope®"

Obesity

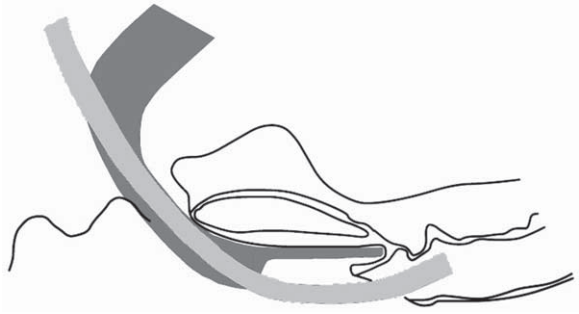
No special measures are taken for the obese or Pregnant patient except that chest prominence might on occasion require twisting of the blade during insertion. The GlideScope® blade is wide and the generous obese tissues are lifted reliably giving a Gr.I view. The GlideScope® was left in place during the connection with the Anesthetic machine and the tube can be seen entering the glottis.

Tips For Endotracheal Tube Passage

1. The endotracheal tube stylet angle is important. The distal end of the ETT must **angulate upward a moderate 60 degrees** to track the blade angulation of the same amount.



2. The **"hesitation of the tube"** is managed by **withdrawing the stylet approximately 4cms**. and **withdrawing the GlideScope® 1-2 cms**. This allows the glottis to drop down and makes the angle of approach of the endotracheal tube more favorable. With continuous gentle advancement intubation will rarely require more than 30-60 secs.



IV. MAINTENANCE

4.1 General Maintenance Information

While the GlideScope® Video Intubation System has been designed and manufactured to high industry standards, it is recommended that periodic inspection be performed to ensure continued safe and effective operation. This section contains information to assist in the effort as well as to serve as a guide to expending unscheduled maintenance.

The exterior of the control unit & cables may be cleaned with a cloth that has been dampened with alcohol or a mild detergent.

4.2 Cleaning the GlideScope® Video Laryngoscope

The disinfection process for this and other devices is divided into two phases. The first phase is a cleaning process that removes all particulates, blood and debris from the device. A common cleaning phase is used for all of the approved processes and phase two, the specialized High level Disinfection process phase is then carried out.

Phase One: Common Preparation Method

First, move the cleaning cap from its storage position to cleaning position as noted in the pictures below.

Figure 1

Cap in cleaning position

Figure 2

Cap in storage position

Now that the cap is in cleaning position, protecting cable connection, the **GlideScope®** is prepared with a wash in a detergent such as Accel KDS Concentrated Instrument Cleaner & Disinfectant, available through Virox Technologies Inc., Manu-Klenz® or an enzymatic debridement agent such as Medzyme® to remove all foreign material from the surface of the device. This allows the active ingredients of the chosen process to reach all of the surface elements of the device. The preferred method that Saturn Biomedical Systems Inc. recommends is Accel KDS.

APPROVED Phase Two Cleaning Options:

LISTED IN PREFERENCIAL ORDER

A. Accel Chemosterilant and High Level Disinfectant

Accel Chemosterilant and High Level Disinfectant uses a stabilized activated peroxide in order to disinfect. It is a new, environmentally friendly product that is produced by a Canadian company, Virox Technologies Inc.

Preparation:
The **GlideScope®** is cleaned as per the Common Preparation Method

Accel Immersion:
The **GlideScope®** electrical connector plug is placed in the connector to protect the terminals and then the **GlideScope®** can be immersed for 35 minutes. Remove from Accel and rinse with sterilized water.

B. Steris®

The Steris system is widely used in hospitals and surgical clinics for Endoscope and instrument sterilization and is ideal for the **GlideScope®** video laryngoscope to produce clinical level of disinfection. The active peracetic acid is approved for the **GlideScope®** video laryngoscope for routine use.

Preparation:
- The **GlideScope®** is washed as per the Common Preparation Method.

Steris® Cycle:
- The medical grade electrical connector cap is taken off of its parking position on top of the **GlideScope®** and is placed into the electrical plug to protect this area. Then the **GlideScope®** is placed into the Steris® machine to commence the cycle. After removal it is ready for service and should be kept in a clean environment.

C. Cidex OPA

The use of Gluteraldehyde based high level disinfection in North America is on a decline and will therefore become less useful. The advantage of this method is rapid onsite turn around with the 12 minute (short) exposure requirement.

Preparation:
The **GlideScope®** is cleaned as per the Common Preparation Method.

Cidex OPA immersion:
The **GlideScope®** electrical connector plug is placed in the connector to protect the terminals and then the **GlideScope®** can be immersed for 12 minutes to complete the OPA requirement. Rinse with sterilized water.

D. Sterrad®

The Sterrad® system produces sterile packaged OR scope and instrument output that is exposed to a vacuum (-400mTorr or less as well as +6-14 Torr) and hydrogen peroxide sterilization chemical. The **GlideScope®** may be treated with this system. The Sterrad® system is widely used in hospitals and surgical clinics for Endoscope and instrument sterilization. and is ideal for the **GlideScope®** handles to produce clinical level of disinfection.

Preparation:
The **GlideScope®** is cleaned as per the Common Preparation Method but for the Sterrad® machine it is necessary to dry the device prior to placement into the processor.

Sterrad® cycle
The washed and dry **GlideScope®** then has the electrical connector plug placed into the connector and Sterrad® chemical indicator strip is then used to tape this firmly in place as in Fig.1. The negative pressures created in the Sterrad® unit during the cycle will result in dislodgement of the plug resulting in exposure of the electrical connector to the hydrogen peroxide. The **GlideScope®** is then placed in a Sterrad® sealing bag and is exposed to the cleaning cycle.

Fig. 1 *Sterrad® indicator tape is applied to the electrical connector cover cap and attached to prevent the cap from coming off during the sterilization cycle. Completion of this cycle yields a sealed sterile **GlideScope®** with an indicator strip that will have changed from **Red** to **Yellow** if the cycle has been completed successfully.*

E. Pasteurization

These systems rely on prolonged exposure to temperatures in the range of 70-75 C and use of an active bath tumbler. The Pasteurmatic is a representative example of such a system and the **GlideScope®** is rendered free of active pathogens using this system.

Preparation:
The **GlideScope®** is cleaned as per the Common Preparation Method but it is hand washed and not submitted to the cleaning phase tumbler often used with the Pasteurmatic.

Pasteurization cycle:
The Electrical connector cap is placed on the connector and the **GlideScope®** can be hung in a bag in the side of the unit during operation or it may be placed into the rotating basket in a protective Pasteurizer bag. The cycle is approximately 30 minutes and gives rapid turnaround producing high-level disinfection.

F. Metricide

To be used by trained personnel under controlled conditions.

PROHIBITED Phase Two Cleaning Options:

A. Autoclaving or Exposure to excessive temperature

Saturn does not approve of autoclaving or exposure to temperatures in excess of 80°C. The **GlideScope®** unit has a silver temperature indicator that will change to black if the unit has had excessive temperature.

4.3 Inspection

The unit should be inspected at regular intervals. It is recommended that a qualified technician perform a visual inspection at least every 6 months.
Inspection points are:

- Obvious external damage
- Condition of the power cord
- Mating integrity of the connectors

4.4 Troubleshooting

SYMPTOM	POSSIBLE CAUSES
Indicator light does not turn green upon pressing the POWER button	a) power supply cord not connected properly b) faulty power cord
"No Signal" warning appears on the control unit screen	a) video cable is not properly connected with either the control unit or the GlideScope® b) faulty video cable

4.5 Contact Information

MANUFACTURER:
Saturn Biomedical Systems Inc.
7033 Antrim Avenue
Burnaby, British Columbia
Canada V5J 4M5

EC REPRESENTATIVE:
Orthofix S.r.l.
via delle Nazioni, 9
37012 Bussolengo (VR)
Italy

4.6 Replacement Parts

To obtain parts or additional information regarding your GlideScope® video intubation system, write, phone or fax:

POST: Saturn Biomedical Systems Inc.
7033 Antrim Avenue
Burnaby, British Columbia
Canada V5J 4M5

EMAIL: info@saturnbiomedical.com

PHONE: 604-439-3009

FAX: 604-439-3039

To ensure prompt service, please include the following information with your order:

- Serial number
- Description of the part and product code
- Quantity desired
- Shipping address and telephone number
- Shipping means (if any)

Parts List:

GS1001-00	*GlideScope® Video Intubation System A* (GlideScope®, Control Unit – with monitor, video cable, power cord, stand, manuals, & reference card)
GS1001-10	GlideScope® Video Intubation System B *(GlideScope®, Control Unit – with monitor, video cable, power cord, IV pole mount, manuals, & reference card)*
GS1001-20	GlideScope® Video Intubation System C (GlideScope®, Control Unit – with monitor, video cable, power cord, manuals, & reference card)
GS1001-30	GlideScope® Bundle A *(GlideScope®, Control Unit – no monitor, video cable, power cord, stand, manuals, & reference card)*
GS1001-40	GlideScope® Bundle B *(GlideScope®, Control Unit – no monitor, video cable, power cord, IV pole mount, manuals, & reference card)*
GS1001-50	GlideScope® Bundle C *(GlideScope®, Control Unit – no monitor, video cable, power cord, manuals, & reference card)*
GS1001-100	GlideScope® Video Laryngoscope
GS1001-200	Integrated GlideScope® Control Unit
GS1001-300	Integrated GlideScope® Control Unit without monitor
GS1001-400	Height adjustable stand
GS1001-500	IV Pole mount
GS1001-600	Video Cable
GS1001-700	Power Cable
GS1001-800	Video Adaptor Cable
GS1001-900	Manual
GS1001-910	Reference Card

GS1001-1000 Packaging

4.7 Storage

Operating Temperature Range:

- 15°C to 45°C
  Indoor Use Only

- Category 2
  Pollution Degree 2

The following are environmental conditions for transportation and storage:

A. Ambient temperature range of –10°C to +70°C
B. Relative humidity range of 10 – 90%

ALL REPAIRS TO BE DONE BY AN AUTHORIZED REPRESENTATIVE OF SATURN BIOMEDICAL SYSTEMS INC.!

V. APPENDIX

5.1 Warranty

Glidescope® Video Laryngoscope System Warranty

Saturn Biomedical Systems Inc. (Saturn) warrants to the original user that its GlideScope® System is free from defect in factory workmanship and materials, such warranty being conditional upon the product having been assembled, operated and maintained by qualified personnel and according to manufacturer instructions.

***Saturn's* liability is limited to repairing and/or replacing without charge at its factory any product or component, which is proven to the satisfaction of *Saturn* to have been defective, which at user's expense has been returned to *Saturn* or authorized service centre within 1 year from date of dispatch. *Saturn's* repair or replacement of any defective product shall be returned to the original user via prepaid freight service and shall constitute fulfillment of its obligations.**

This Warranty applies to the manufactured products which are shown by the purchaser to have been originally defective and shall not apply to products which must be repaired or replaced due to misuse, negligence, wreckage, accident, any act of god or to products which have been repaired or altered outside of seller's factory or one of its authorized service centres unless authorized solely by *Saturn*. All physical damage must be reported to *Saturn* with proof of receipt. Failing to do so may negate any claims.

Saturn* shall not be liable for loss, damage, or expense, consequential or otherwise from the use of its products or from any other cause. THIS WARRANTY SUPERSEDES AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED OR CONDITIONS WHETHER STATUTORY OR OTHERWISE AS TO QUALITY AND FITNESS FOR ANY PURPOSE FOR WHICH THE PRODUCTS ARE SUPPLIED. No person, agent or dealer is authorized to give any warranty on behalf of Saturn or to assume for seller any other liability in connection with any of its products unless made in writing and signed by an officer of *Saturn.

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